Changes in glycaemic control, blood pressure and lipids 5 years following laparoscopic adjustable gastric banding combined with medical care in patients with type 2 diabetes

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DOI:
10.1111/cob.12244

Changes in Glycaemic control, Blood Pressure and Lipids Five Years Following Laparoscopic Adjustable Gastric Banding Combined With Medical Care In Patients With Type 2 Diabetes: A Longitudinal Analysis

Running title: "Gastric banding in Type 2 Diabetes"

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Keywords: Bariatric Surgery, Laparoscopic adjustable Gastric Band, Type 2 Diabetes Mellitus, Metabolic Syndrome

Article type: Original article

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Tables - 4; Figures - 2
References: 24
Word count: 3248

What is already known:

- Type 2 diabetes is a chronic disease in which treatment targets in regard to glycaemic control, blood pressure, and lipids in combination are often not achieved in real life practice.
- RCTs have shown the superiority of bariatric surgery compared to medical treatment in patients with Type 2 diabetes
- Trials assessing the impact of Laparoscopic Adjustable Gastric Banding (LAGB) were of up to 3 years duration and mainly focussed on the impact of surgery on weight and glycaemic control.

What this study adds:

- The impact of LAGB and multidisciplinary care on patients with type 2 diabetes and obesity in real life setting with an average of 5 years follow up
- LAGB combined with multidisciplinary care results in significant improvements in weight, glycaemic control, blood pressure and lipids that were sustained over the 5 years period despite reduction in the use of insulin treatment.
- Higher pre-operative glycosylated haemoglobin was associated with greater improvements in glycaemic control post operatively. Higher pre-operative body mass index did not predict changes in glycaemic control, Blood pressure or lipids after LAGB

Abstract

Aims

The long-term outcomes of weight loss maintenance induced by Laparoscopic Adjustable Gastric Band followed (LAGB) by multidisciplinary medical care in patients with type 2 diabetes mellitus (T2DM) (beyond 3 years) are scarcely reported. Study aims were to determine the longer term metabolic outcomes following LAGB combined with medical care in patients with T2DM.

Methods

A longitudinal analysis of 200 adults with T2DM who had LAGB between 2003 and 2008 and were followed-up till 2013 at a single bariatric unit in a tertiary UK centre.

Results

Two-hundred patients (age 47±9.7 years, body mass index (BMI) 52.8±9.2 Kg/m^2, glycosylated haemoglobin (HbA1c) 7.9±1.9 % (62.8 mmol/mol), women n=123 (61.5%), insulin treatment n=71 (35.5%)) were included. The mean follow-up was 62.0 ± 13.0 months (range 18 to 84 months). There were significant reductions in body weight (- 24.4% ± 12.3% (38 ± 22.7kg)), HbA1c (- 1.4± 2.0 %), systolic blood pressure (BP) (-11.7±23.5 mmHg), total cholesterol and triglyceride levels. The proportion of patients requiring insulin reduced from 36.2% to 12.3%. The overall band complication rate was 21% (21 patients).

Conclusions

LAGB when combined with multidisciplinary medical care significantly improved metabolic outcomes in patients with T2DM independent of diabetes duration, and baseline BMI over 5 years. Diabetes duration and baseline BMI did not predict changes in glycaemic control, BP or lipids following LAGB.

Introduction

The impact of bariatric surgery in patients with Type 2 diabetes mellitus (T2DM) has attracted increasing attention[1-3]. Several studies showed that laparoscopic adjustable gastric banding (LAGB) was superior to medical treatment in patients with T2DM in terms of weight loss, and glycaemic control, and that LAGB was associated with favourable impacts on retinopathy and chronic kidney disease[4-7]. Nonetheless, the longer term outcomes of weight loss maintenance following LAGB in patients with T2DM (beyond 3 years) are scarcely reported. Furthermore, there is limited evidence assessing the impact of long-term weight loss following LAGB on lipids and blood pressure (BP) in patients with T2DM. Studies have shown that patients randomised to LAGB achieved greater diabetes remission and greater HbA1c reductions compared to medical care (33% of patients undergoing LAGB reached the target HbA1c level below 6.5% at one year, compared to 23% in the medically managed cohort; 12 patients reaching diabetes remission at 2 years compared to 2 patients in the medically treated group)[8, 9]. There is limited 'real life' data available in the literature about the effect of LAGB combined with a multi-disciplinary team (MDT) approach on the management of this group of patients[10]. Therefore there is a need to assess the impact of LAGB combined with MDT care on a large heterogeneous group of patients with T2DM over a longer period of time.

Our primary aim was to determine the longer term metabolic outcomes following LAGB combined with medical care in patients with T2DM. A secondary outcome was to assess the predictors of change in the above-mentioned metabolic parameters.

Methods

We conducted a longitudinal analysis of patients with T2DM who received LAGB at a single tertiary bariatric centre between 2003 and 2008. Of 1815 patients, 200 patients (11.01%) had a diagnosis of T2DM with a minimum of one year of follow-up and were included. Data was prospectively collected on a yearly basis till 2013 using the hospital's electronic patient records and from the primary care physicians' when needed. Pre-operation assessment was carried out within 6 weeks of the date of surgery. It was at this point that blood samples were taken therefore these results were taken as baseline markers. For weight and blood pressure the baseline value was the date of surgery. The last available clinical observation was included in the analysis.

Patients were considered to have T2DM if they either had a physician diagnosis, a HbA1c >= 6.5%, a fasting plasma glucose of ≥7.0mmol/L or random plasma glucose of ≥11.1mmol/L with symptoms or on two occasions without symptoms[11]. Hypertension was defined as a known history of hypertension, the use of anti-hypertensive medication at baseline, or if the patient was found to have a persistently raised BP above 140/90mmHg[12].

Surgical procedures and post-operative management: Procedures were performed by a single surgical team with standard technique previously described[13]. Three different bands were used over the study period (Allergan Vanguard®™, Allergan AP large®™ and Swedish bands®™). Patients underwent the same standard peri-operative, and postoperative management. For follow-up, patients were seen at 6 weeks, 3 months, 6 months, 6 monthly until 2 years, and then annually or on request. Patients had fluoroscopy-guided bands adjustments at 3 and 6 months and thereafter as required. The multidisciplinary team

(MDT) included surgeons, dieticians, radiologists and physicians. MDT meetings were scheduled weekly. Patients were discussed in the MDT at the request of the health care professional (HCP) who had contact with the patient. There were a variety of reasons for which patients were discussed in the MDT including: excessive or inadequate weight loss at the discretion of the HCP, gastrointestinal symptoms, concerns regarding metabolic control at the discretion of the HCP or the patient, disordered eating, or the patients' request. The MDT discussed different management options such as dietary modifications, addressing specific behavioural issues, band fills/adjustment and optimisation of the medical management. Following the MDT decision, the appropriate management plan was initiated with the involvement of the appropriate speciality(ies) as required. MDT decisions regarding the management of glycaemic control and cardiovascular risk factors were implemented either via the primary care physician, or the treating physician or Weight management specialist depending on the clinical situation.

The analysis was performed as part of health service evaluation assessing the outcomes of LAGB at our centres and hence ethical approval was not required.

Statistical methods: Analysis was performed using Statistical Package for Social Sciences 22 (SPSS® Chicago, IL). Data were expressed as mean and standard deviation (SD) and ranges or frequencies depending on data distribution. Weight loss was described as absolute BMI loss, total body loss and as percentage excess BMI loss[14]. To assess the impact of LAGB on the metabolic parameters, data were presented on yearly basis and the differences between baseline and study-end were assessed using the paired t test or the Wilcoxon signed ranks test depending on data distribution. The latest available follow-up measurement was inserted as the study-end value. For missing data we have performed a sensitivity analysis using the baseline observation carried forward method as this is likely to represent worst case scenario, i.e. no change in any of the measured outcomes after LAGB. We have also performed a sensitivity analysis in a subgroup of study participants who are confirmed to still have the LAGB at study-end. The follow-up duration for any of the particular outcome measures was defined as the time between baseline measurements and the final available measurement.

To assess predictors of changes in HbA1c, BP, lipids and weight multiple linear regressions were used. The outcome measure was the change in the metabolic parameter of interest. The independent variables included demographics, baseline values of the outcome measure, other factors that are biologically related to the outcome measure and the duration of follow-up for the particular outcome measure. The enter method was used in all the regression models. All linear regression assumptions were adhered to. We assessed the weight loss across quartiles of HbA1c change post bariatric surgery. We also assessed the proportion of patients meeting the glycaemic control criteria for the American Diabetes Association (ADA) and the International Diabetes Federation (IDF) criteria for optimisation of metabolic state after bariatric surgery(11, 15). We also assessed the frequency of weight re-gain following achieving nadir weight following LAGB and assessed the relationship between glycaemic control and weight regain using the independent t test or the Mann-Whitney U test depending on data distribution. Statistical significance was defined as $p<0.05$.

Results

A total of 200 patients with obesity were included in the analysis, mostly middle-age women. Mean length of follow-up for weight was 62.0±13.0 months (range 18-84months), 67.2±13.3 months (range 12-96 months) for HbA1C, 59.6±8.3 months (range 24-84months) for BP, 48.2±22.0 months (range 6-96months) for triglycerides and 61.70±19.30 months (range 12-96months) for total cholesterol. Baseline characteristics are summarised in table 1.

Weight loss (figure 1a)

LAGB resulted in progressive weight loss during the follow-up period with almost 70% of the total weight loss occurring in the first year. At one year mean total weight loss was 14.9±22.5% (26.3±15.4kg), mean BMI loss was 9.2±5.3kg/m^2 and mean excess BMI loss was 34.0±17.6% with further reduction in weight by the end of the follow-up (Table 2,figure 1). A small proportion of patients (5/200) failed to lose any weight in the first 12 months; however there were only 2/192 patients who failed to demonstrate weight loss at the end of year 4. A weight loss nadir was achieved at 41.2±15.8 months, with only 3.5% and 0.5% of patients regaining more than 25% and 50% of their weight loss respectively. 8% of patients lost less than 10% of their weight, while 92% of patients maintained more than 10% weight loss, 76.6% lost more than 15% of their weight and 61% lost more than 20% of their weight at latest follow-up.

Glycosylated Haemoglobin (figure 1b)

HbA1c decreased progressively following LAGB from 7.9±1.9% (62.8 mmol/mol) pre-operatively to 6.5±1.6% (47.5 mmol/mol) by study-end (Table 2). The improvements in HbA1c occurred despite a reduction in the number of patients requiring insulin treatment and insulin dosages (Figure 2). Information regarding the amount of oral metformin taken by each patient was also recorded. The mean dose was 1931 mg pre-operatively falling to 1534 mg at the end of the study period. The number of patients on metformin reduced from 147 pre-operatively to 31 patients at the end of the study. There were 8.6% of patients with a HbA1c <6% (42.1 mmol/mol) pre-operatively increasing to 40.7% by study-end.

HbA1c improvements expressed as quartiles (quartile 1:≤-2.4%, quartile 2: -2.39 to -1.3%, quartile 3: -1.29 to -0.30%, quartile 4:≥-0.29%) revealed that final HbA1c across the quartiles were 6.1± 1.2%, 6.2 ± 1.5%, 6.2±1.2% and 7.8±1.8% for 1st, 2nd, 3rd and 4th quartile respectively. The associated weight loss associated with the quartiles of HbA1c changes were 23.0±11.2%, 25.4±13.3%, 23.7%±11.7% and 22.4±12.7% for quartiles 1-4 respectively (p=0.7 for the trend). Change in HbA1c did not differ between those who stopped insulin vs. patients who continued insulin treatment (-1.5±2.0% vs. -1.4±2.4%, p= 0.93). Similarly, there was no difference in HbA1c change between patients who regained ≥10% following nadir weight post LAGB and patients who did not regain weight (-1.4±2.8 vs. -1.4±1.9, p=0.83).

Blood pressure (figure 1c, d)

Following LAGB there was significant reduction in systolic and diastolic BP (Table 2). Most of the decrease in systolic BP occurred in the first year which was maintained during follow-up. Similarly, the decrease in diastolic BP was mostly in the first year. The proportion of patients who had a BP <130/80mmHg at baseline was 17.7% (33/186) increased by study-end to 31.7% (52/164).

Lipids (figure 1e, f)

Total cholesterol and triglycerides levels improved modestly by the end of the follow-up (Table 2). The improvements in total cholesterol occurred from year 3 post LAGB. Triglycerides levels improved within the first year post LAGB. The percentage of patients achieving a total cholesterol levels <150mg/dl or 4mmol/l increased from 28.5% preoperatively to 32.0%, 30.8%, 36.5% and 35.0% at the end of years 1,2,3, and 4 respectively.

Predictors of changes in metabolic parameters

A summary of the linear regression analysis assessing the predictors of the change in HbA1c, BP and lipids can be found in Table 3 (below). Pre-operative BMI was not a significant predictor to changes in any of the metabolic parameters. Changes in weight were also not a predictor to any of the changes in metabolic parameters except diastolic BP. When percentage weight loss was assessed in quartiles (quartile1:≤-29.6%, quartile 2:-29.59 to -23.78%, quartile 3:-23.77 to -15.83%, quartile 4:≥-15.82%), there was no difference in HbA1c changes from baseline across the weight loss quartiles (-1.50 ±1.6%, -1.7±2.2%, -1.1±1.7%, -1.5±2.5%, p=0.64 using ANOVA and p=0.29 using Kruskal-Wallis test).

Lower pre-operative HbA1c, pre-operative insulin treatment and older age were associated with less change in HbA1c with all levels of weight loss after LAGB. For systolic BP the main predictor was pre-operative systolic BP values with higher pre-operative systolic BP associated with greater decreases in BP for all levels of weight loss after LAGB. Greater weight loss was associated with greater decreases in diastolic BP after LAGB. Greater improvements in HbA1c were also associated with greater improvements in total cholesterol and triglycerides levels for all levels of weight loss after LAGB. Higher pre-operative total cholesterol and triglyceride levels were associated with greater reduction in their respective levels after LAGB.

Safety and surgical complications

At 2 years post LAGB, there was no mortality and the mean length of stay was 1.3±3.4 days (range 0-49 days) with overall operative complication rate was 1% (2 patients had the band removed due to slippage).

We attempted to contact all patients in 2013 but only managed to make successful contact in 100 patients (out of 200). Out of 100 patients, 88 still had the band in-situ by 2013. In the remaining 12 patients, 3 patients were converted to Roux-en-Y gastric bypass (RYGB) and 9 patients had the band removed due to complications such as erosions, infection, slippage, pouch dilatation, intractable vomiting or patient choice. In this subgroup of 100 patients there was no mortality, with an overall operative complication rate over the entire study duration of 21% (21 patients). These complications included eight punctured bands/tubes, three band infections, seven partial band slippages, one port site bleed, and two wound infections. They were all successfully treated, repaired or replaced as appropriate with no long-term consequences for patients.

Sensitivity analysis

Using the baseline observation carried forward, we have repeated the same analysis that we detailed in Table 2 and that did not change the findings that were presented in Table 2 except for diastolic BP which did not reach significance (Table 4). We have performed another sensitivity analysis using the data of the 88 patients who we know still have the band and that did not change the findings except that changes in diastolic BP which did not reach significance.

Discussion

This study showed that LAGB combined with post-operative multidisciplinary care was effective and safe in patients with T2DM and obesity resulting in significant improvements in weight, BP, lipids and HbA1c that was maintained after an average of 5 years follow-up. The significant improvement in metabolic parameters is likely to reflect the use of the LAGB as an adjunct to holistic care of patients with diabetes in addition to a highly experienced MDT of surgeons, dieticians, radiologists and physicians[16, 17].

Previous RCTs showed that LAGB was superior to medical treatment and lifestyle intervention in patients with T2DM over a 1-3 year period[5, 18, 19]. Our results reflect the use of LAGB in conjunction with input from an experienced MDT which extended the improvements in weight loss and glycaemic control at 5 years follow-up. This may explain why the HbA1c reductions in our study were greater than the longest RCT to date (3 years) despite having similar baseline HbA1c between both studies and a shorter diabetes duration in the RCT compared to our study. The weight loss we achieved was also greater compared to the RCT (25%vs.15%); nonetheless in our data the amount of weight loss was not a predictor of change in HbA1c. This could be due to patients losing less weight still profiting from good multidisciplinary input into their diabetes treatment[17].

The improvements in HbA1c and weight were progressive over the follow-up which is different from other studies showing peak response at 1-2 years post-LAGB[18, 20]. This could be due to our differences in study population, and the study settings and follow-up protocols which integrated optimal LAGB with medical care.

The decline in LAGB popularity is partly driven by reports of higher rate of long-term complications compared to other bariatric procedures and the need for revisional surgery in patients with LAGB. Lazzati et al reported on more than 50 000 patients who received LAGB and showed that 28% had band removal at 5 years[21]. In our study 12 of the 100 patients that were contactable in 2013 underwent revisional surgery or had band removal within the average 5 years follow-up. Such discrepancy can be explained by inter-centre differences in expertise and in technological advances in the band. In fact, Lazzati et al showed that there was a significant “centre” effect on band survival (Adjusted HR 0.79, 95%CI 0.7–0.89, $p < 0.001$; HR were for band removal for centres that perform > 50 bands/year vs. <= 50 per year)[21] . Another longitudinal study showed that the need for revisional procedures in LAGB patients declined as the technique evolved (40% revision rate for proximal gastric enlargements in the first 10 years, vs. 6.4% in the past 5 years)[22]. Our centre has longstanding experience providing LAGB for patients with morbid obesity for the last 16 years which resulted in the developments of robust local surgical, medical, dietetic and radiological expertise.

Examining the predictor of metabolic outcomes in our study suggests that pre-operative factors such as higher HbA1c levels, or higher BMI or diabetes duration should not be barriers to patients undergoing LAGB as they do not predict worse outcomes, especially when LAGB is being combined with multidisciplinary input. Even the use of insulin which was associated with less post-LAGB HbA1c reductions should not be considered a barrier to receiving LAGB as many of these patients became insulin-free during the follow-up or there were significant reductions in insulin requirements.

These observations raised the question of how many of our patients were interested in long-term weight loss maintenance as a primary treatment to improve their glycaemic and metabolic control and how many wanted weight loss for other reasons. Our study did not prospectively capture this information, but 36.2% of our patients pre-surgery would have been considered to have good glycaemic control (HbA1c<7% (53.0 mmol/mol)) and 30.3% to have poor glycaemic control (HbA1c≥8.5% (69.4 mmol/mol)). After surgery 69% satisfied the ADA criteria for good glycaemic control (HbA1c<7% (53.0 mmol/mol)) and 42.7% achieved a HbA1c<6% (42.1 mmol/mol). However, only 10.3% met all the criteria of the IDF to signal optimal metabolic control when considering weight loss, glycaemic control, BP control and control of dyslipidaemia[23]. These results with LAGB are similar to groups who used other bariatric procedures[15], suggesting that despite our integration of LAGB with a dedicated team providing multidisciplinary input, more can be done with the optimal use of medication to get even better control of weight, glycaemic control, high BP and dyslipidaemia.

The design of this study does not to differentiate the effects of LAGB from medical care due to the lack of control arm. However, our results show the benefits of such combined approach in real life. Despite, loss of follow-up we still had an average follow-up of 5 years with more than 80% of patients having data for most study parameters and the sensitivity analysis did not change our findings. There is also inherent selection bias for patients who specifically chose LAGB as opposed to alternative procedures or no procedures. Another limitation of this study is the lack of data regarding the use of oral hypoglycaemic, anti-hypertensives and lipid lowering treatments during the follow-up, but nonetheless it was clear that the metabolic improvements occurred in the context of less insulin usage. Our findings showed that LAGB combined with multidisciplinary care resulted in significant weight loss and improvements in HbA1c despite the less use of insulin and metformin after LAGB. The improvements observed in BP and lipids can be related to the use of pharmacotherapy as data regarding BP and lipid lowering medications are not available in this trial. However, this is unlikely to be the case as weight loss has been shown in previous trials to result in improvements in BP and lipids(24) and previous RCTs showed the favourable impact of LAGB on BP and lipids(5). We also only managed to successfully contact 100 out of 200 patients to ensure that they still have the band but the sensitivity analysis including the 88 patients who we know that still have the band in situ showed similar results to the total study population.

The study also has its strengths including the long follow-up duration and high retention rate in relation to patient's metabolic data. The LAGB and post-LAGB care were performed in an experienced surgical centre with a good set up for LAGB which was integrated with state of the art MDT.

In conclusion, weight loss after LAGB combined with multidisciplinary input is helpful to patients with obesity and T2DM and result in significant improvements to glycaemic control and multiple cardiovascular disease risk factors over 5 years period. Pre-operative BMI and diabetes duration did not predict changes in HbA1c, BP or lipids following LAGB in the context of multidisciplinary care following the LAGB.

Acknowledgment

AAT is a Clinician Scientist supported by the National Institute for Health Research (NIHR) in the UK. The views expressed in this publication are those of the author(s) and not necessarily those of the NHS, the National Institute for Health Research, or the Department of Health. AAT and RS conceived the design of the study. PM and VC collected data. All authors analysed the data, were involved in writing the paper and had final approval of the submitted and published versions.

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Number of patients	200
Age (years)	47 (9.7; 25 - 74)
Gender (male/female)	77/123
Duration of diabetes (months)	82.8 (14.0; 53.8 - 127.3)
Pre-operative weight (Kg)	150.3 (29.8; 93 - 240)
Pre-operative BMI (Kg/m^2)	52.8 (9.2; 35.9 - 81.8)
HbA1c (%) (185 patients)	7.9 (1.9; 3.7 - 13.3)
Systolic BP (mmHg)	140.3 (17.7; 140 - 196)
Diastolic BP (mmHg)	96.0 (10.9; 90 - 114)
Hypertension (known hypertension or SBP≥140 or DBP≥90 or both) (186 patients)	104(55.9%)
Drug treatment:	
Insulin number (%)	71 (35.5)
Metformin number (%)	147 (73.5)

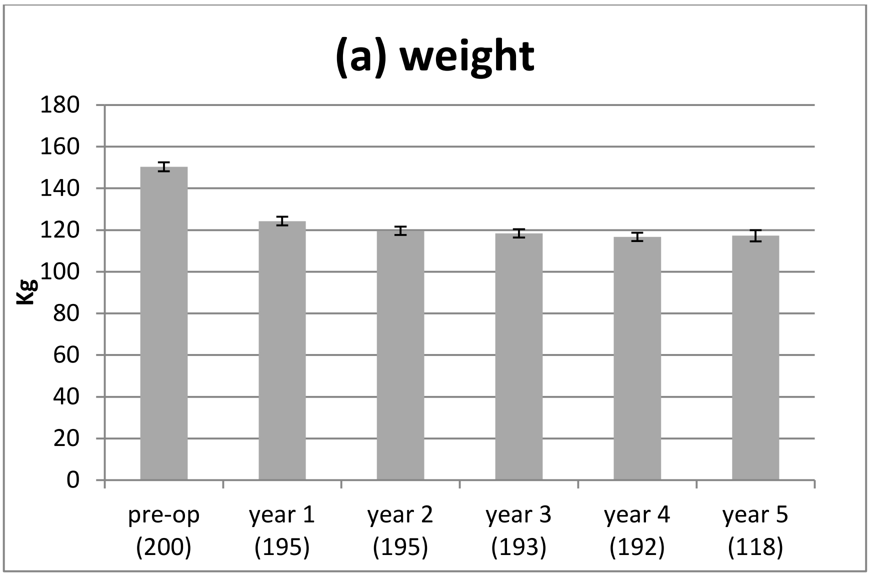
Table 1. Baseline demographics for the study population. Data presented as mean (standard deviation; range) or n (frequency). BMI - body mass index, HbA1c - glycosylated haemoglobin, BP - systolic blood pressure, BP - diastolic blood pressure.

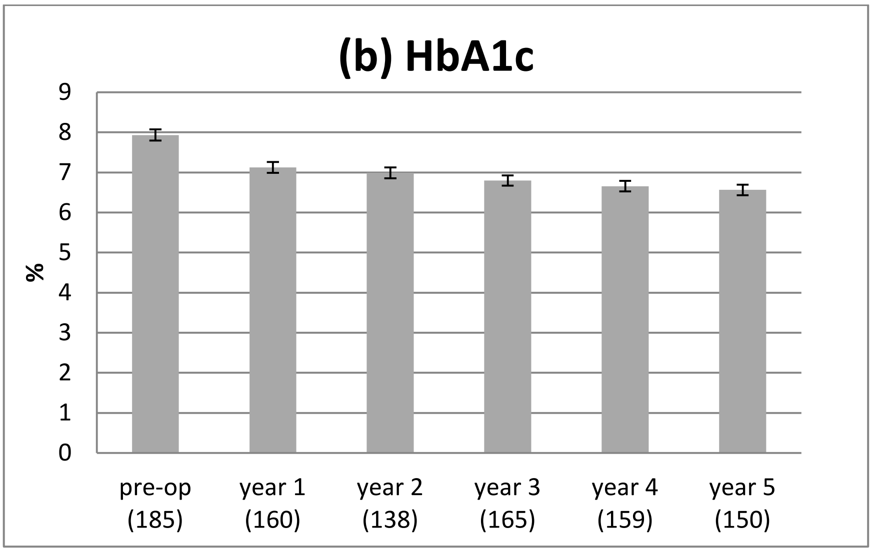
	Baseline	No. Of patients (%)	1 year	No. Of patients (%)	Latest time-point	No. of patients (%)	P value*
HbA1c (%)	7.9 ± 1.9	185 (92.5)	7.1 ± 1.7	160 (80)	6.5 ± 1.6	170 (85.5)	<0.001
Weight (kg)	150.3 ± 29.8	200 (100)	124.3 ± 27.8	195 (97.5)	112.8 ± 25.7	200 (100)	<0.001
Systolic BP (mmHg)	140.1 ± 17.7	186 (93)	129.2 ± 13.5	179 (89.5)	126.9 ± 9.6	183 (91.5)	<0.001
Diastolic BP (mmHg)	82.2 ± 10.8	186 (93)	77.9 ± 8.6	179 (89.5)	79.7 ± 5.3	183 (91.5)	0.007
Total cholesterol (mmol/l)	4.6 ± 1.1	179 (89.5)	4.6 ± 1.0	166 (83)	4.2 ± 1.1	169 (84.5)	0.006
Triglycerides (mmol/l)	2.0 ± 1.0	157 (78.5)	1.8 ± 1.0	139 (69.5)	1.5 ± 0.7	133 (66.5)	<0.001

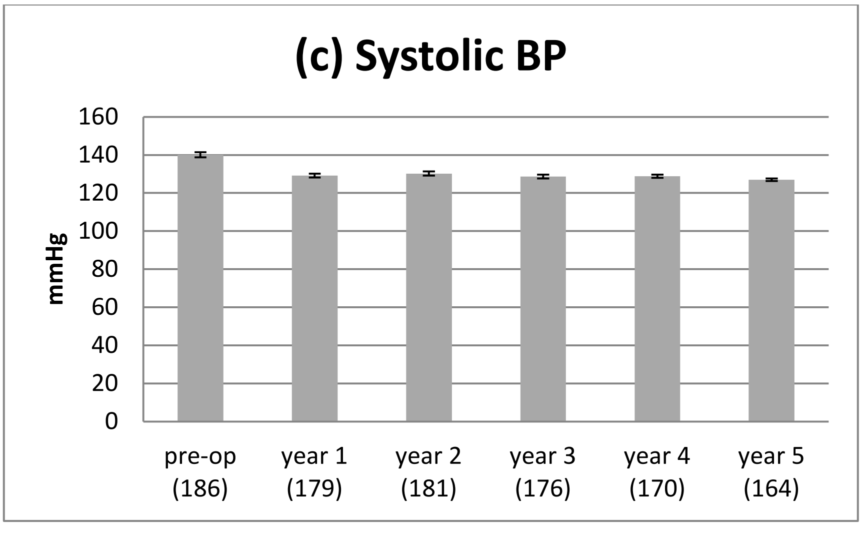
Table 2. Changes in metabolic parameters from baseline to final available reading. Data presented as mean ± standard deviation. *p-value paired t-test between baseline and latest value available.

Outcome measure	Variable	B value	P value
Change in HbA1C **R^2 = 0.470**	Pre-op HbA1c	-0.694	**<0.001**
	Insulin therapy	0.682	**0.007**
	Age	0.023	**0.037**
	Gender MF	-0.299	0.156
	Diabetes duration	0.003	0.112
	% change in weight	0.008	0.359
	Pre-op BMI	-0.005	0.710
Change in Systolic BP **R^2 = 0.758**	Age	0.066	0.425
	Gender MF	2.777	0.082
	Diabetes duration	0.012	0.348
	% change in weight	0.069	0.299
	Pre-op BMI	0.026	0.780
	Pre-op HbA1c	0.936	0.101
	Change in HbA1c	0.993	0.090
	Pre- op Systolic BP	-0.869	**<0.001**
Change in diastolic BP **R^2 = 0.820**	Pre-op Diastolic BP	-0.941	**<0.001**
	Age	-0.057	0.218
	Gender MF	2.096	**0.016**
	Diabetes duration	0.005	0.458
	%change in weight	0.089	**0.015**
	Pre-op BMI	0.008	0.871
	Pre-op HbA1c	-0.217	0.487
	Change in HbA1c	-0.191	0.546
Change in cholesterol **R^2 = 0.367**	Age	-0.012	0.167
	Gender MF	-0.123	0.459
	Diabetes duration	0.000	0.916
	% change in weight	0.003	0.667
	Pre-op BMI	0.008	0.425
	Pre-op HbA1c	0.052	0.399
	Change in HbA1c	0.165	**0.009**
	Pre-op cholesterol	-0.582	**<0.001**
Change in triglyceride **R^2 = 0.556**	Age	-0.012	0.055
	Gender MF	0.102	0.386
	Diabetes duration	0.000	0.638
	%change in weight	0.005	0.244
	Pre-op BMI	0.006	0.400
	Pre-op HbA1c	0.086	**0.044**
	Change in HbA1c	0.059	0.179
	Pre-op triglyceride	-0.601	**<0.001**

Table 3. Predictors of changes in metabolic parameters using linear regression. Change in each variable was calculated as study end value - baseline value. BP: blood pressure; BMI: body mass index, MF: male/female.


(a) weight
180
160
140
120
100
80
60
40
20
0
Kg
pre-op (200)
year 1 (195)
year 2 (195)
year 3 (193)
year 4 (192)
year 5 (118)


(b) HbA1c
9
8
7
6
5
4
3
2
1
0
%
pre-op (185)
year 1 (160)
year 2 (138)
year 3 (165)
year 4 (159)
year 5 (150)


(c) Systolic BP
160
140
120
100
80
60
40
20
0
mmHg
pre-op (186)
year 1 (179)
year 2 (181)
year 3 (176)
year 4 (170)
year 5 (164)

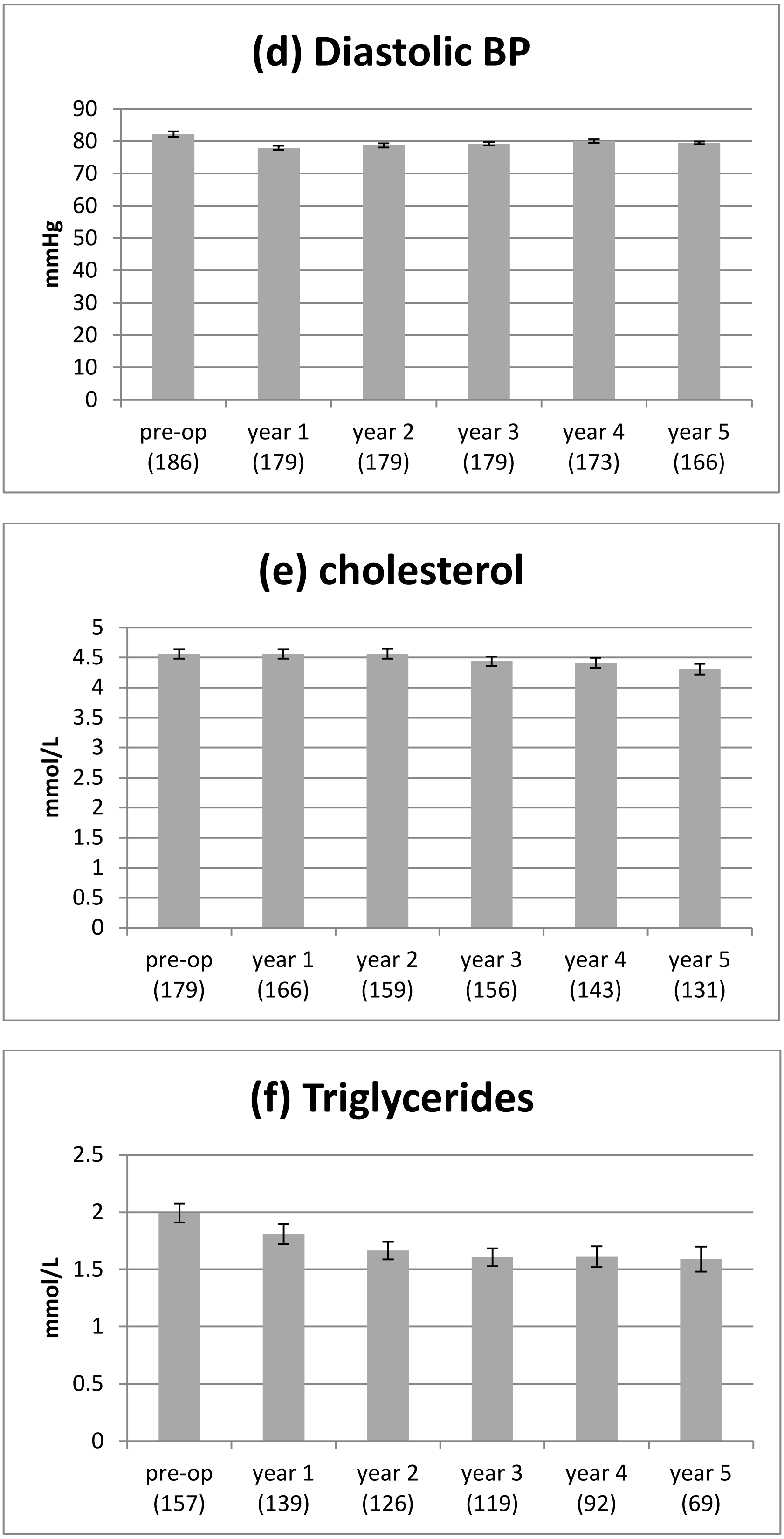
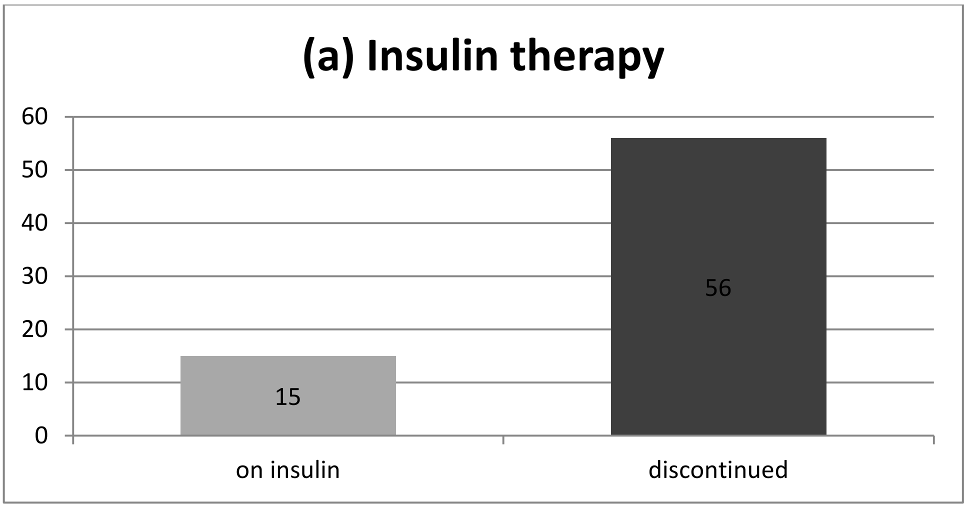


Figure 1. Changes in each variable over the follow up period. Error bar represent standard error and numbers in brackets indicate the number of patient for which data was available at each time point.



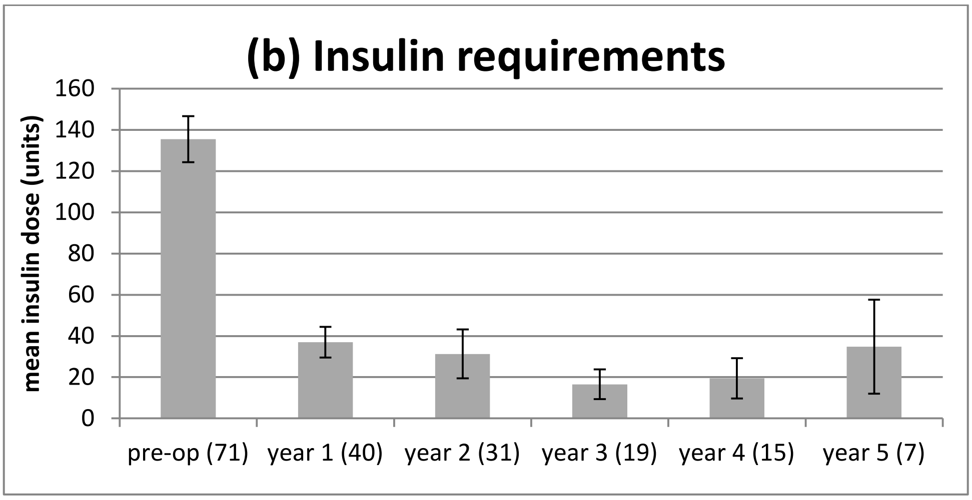


Figure 2. (a) The proportion of the 71 patients who were on insulin at the start of the study period who subsequently discontinued therapy by the end of year 4. (b) Changes in the mean insulin dose of patients still on this medication up to five years from baseline. Numbers in brackets indicate number of patients at the end of each year. Error bars represent standard error.

	Baseline	No. Of patients (%)	Latest time-point	No. of patients (%)	P value*
HbA1c (%)	7.7 ± 1.9	74 (84.1)	6.3 ± 1.6	74 (84.1)	0.000
Weight (kg)	145.9 ± 27.6	79 (89.8)	112.0 ± 26.9	79 (89.8)	0.000
Systolic BP (mmHg)	138.7 ± 16.2	74 (84.1)	126.8 ± 11.5	74 (84.1)	0.000
Diastolic BP (mmHg)	81.7 ± 9.0	74 (84.1)	79.7 ± 5.6	74 (84.1)	0.094
Total cholesterol (mmol/l)	4.6 ± 1.1	67 (76.1)	4.2 ± 1.0	67 (76.1)	0.004
Triglycerides (mmol/l)	1.8 ± 0.6	62 (70.5)	1.5 ± 0.6	62 (70.5)	0.001

Table 4. Changes in metabolic parameters from baseline to final available reading for the 88 patients who still had their band in situ. Data presented as mean ± standard deviation. *p-value paired t-test between baseline and latest value available.